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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/548,081	04/12/2000	Florencio Zaragoza Dorwald	5390.200-US	5691

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EXAMINER

LIU, HONG

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 01/09/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/548,081

Applicant(s)
Dorwald et al.

Examiner
Hong Liu

Art Unit
1624



-- **Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on Dec 3, 2001

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1, 2, 5-32, 34-37, 46, 48, and 64-67 is/are pending in the application

4a) Of the above, claim(s) _____ is/are withdrawn from consideration

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1, 2, 5-32, 34-37, 46, 48, and 64-67 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirements

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☒ All b) ☐ Some* c) ☐ None of:

1. ☒ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

19) ☐ Notice of Informal Patent Application (PTO-152)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

20) ☐ Other: _____

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DETAILED ACTION

Claims 1, 2, 5-32, 34-37, 46, 48, and 64-67 are pending in this application.

This action is in response to the applicants' amendment and reply filed on December 3, 2001.

Response to Arguments

Applicants' arguments filed on December 3, 2001 have been fully considered but they are not persuasive. Rejections to Claims under 35 U.S.C. 112, first paragraph, 102, and 103 are maintained.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claims 1-3, 5-44, 46, and 48 remain rejected under 35 U.S.C. 112, first paragraph, for reasons already made of record notwithstanding applicants' traverse. The claims are still not commensurate in scope as to the diversity of Markush groups, aromatic groups, heteroaromatic and heterocyclic groups which all permit further substitution on the purine ring. The instant case is similar to *In re Lund*, 153 USPQ 625, in which the Court agreed the specific aldehyde reactants mentioned in the specification fell within a limited range and thus far short of the claims' scope. Applicants urge that the compounds embraced herein are active as H3 receptor antagonists, and thus all of the functional moieties and heterocyclic/aromatic groups which are embraced by these

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claims have the activity of inhibiting H3 receptors. However, no reasons and evidence have been provided to support applicants' position. Applicants have not provided adequate information that the instant compounds **as an entire class** have the required activities needed to practice the invention, and therefore, there is no reasonable basis for assuming that the variety of substituents embraced by the claims will all share the same physiological properties. See MPEP 2164.03 for enablement requirements in cases directed to structure-sensitive arts such as the pharmaceutical art. Note also the quote taken from *Surrey*, previously cited, "Manifestly, a disclosure which does not adequately establish compounds as useful for an asserted purpose does not adequately describe "how to use" these compounds either." Also note the quote taken from *In re Cavallito* 127 USPQ 202 which was cited in *Surrey*, previously cited, at page 730; "...where the applicant seeks to obtain a monopoly in exchange for his disclosure of a group of compounds there should be a disclosure which gives reasonable assurance that all, or substantially all of them are useful...An applicant is not entitled to a claim for a large group of compounds merely on the basis of a showing that a selected few are useful and a general suggestion of a similar utility in the others." Note Markush claims are subject to rejection based upon the lack of supporting disclosure when the "working examples" fail to include written description(s) which teach how to make and use Markush members embraced thereby in full, clear and exact terms. See *In re Fouche*, 169 USPQ 429. Furthermore, applicants rely on the working examples in the specification, but as mentioned before, these examples are limited to a homogenous group of compounds. While every claimed embodiment need not be shown to possess the requisite activity

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needed to practice the invention, there must be a showing that is **representative** of the claimed scope. Applicants provide no sound reasoning why one skilled in the art should or would accept the working examples drawn to compounds wherein R5 and R6 are hydrogens, A is a bond, alkyl, R3 or R4 is hydrogen, methyl, alkyl-substituted phenyl, spiro, alkyl as being representative. Note In re Armbruster, 185 USPQ 152, wherein it was stated that a specification which “describes the invention as broadly as it is claimed...does not necessarily also “enable” one skilled in the art to make or use the claimed.

The scope of a functional group which can be converted to hydrogen *in vivo* remains not enabled. Applicants provide no guidance as how the compounds are made more active *in vivo*. The choice of a “functional group” will vary from drug to drug. Although there listed functional groups that are alleged to be able to be converted to hydrogen in the specification, the scope of the claim is much broader than the listed examples. Therefore, more than minimal routine experimentation would be required to determine which prodrug will be suitable for the instant invention.

In claims 46 and 48, instant claim language embraces disorders not only for treatment but also for PREVENTION which is not remotely enabled. It is presumed in the prevention of disease and/or disorders claimed herein there is a way of identifying those people who may develop diseases related to overweight, etc. There is no evidence of record which would enable the skilled artisan in the identification of the people who have the potential of becoming afflicted with the disorders claimed herein.

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Claims 1, 2, 5-32, 34-37, 46, 48, and 64-67 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In an effort to overcome the 102 and 103 rejection, applicants have added more provisos in claim 1. These provisos lack description. Even negative limitations require a description. The MPEP at 2173.05(I) Negative Limitation states “Any negative limitation or exclusionary proviso must have basis in the original disclosure. See *Ex parte Grasselli*, 231USPQ 393 (Bd. App. 1983) *aff’d* mem., 738 F. 2d 453 (Fed. Cir. 1984)” and further, “Any claim containing a negative limitation which does not have basis in the original disclosure should be rejected under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement.” in the instant case, the new concept that has been introduced by the proviso is the specific relationships between R1, R2, R3, R4, R5, R6 and -X-Y-A-Z. This specific relationship of connectivity was previously not disclosed. This notion that the definition of one variable depends on the definitions of other variables is new. The definition of a variable is no longer independent.

The rejections to claims under 35 U.S.C. 112, second paragraph, is hereby withdrawn. Applicants have either amended or deleted the claims to overcome the rejection.

Claim Rejections - 35 USC § 102

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Rejection to claims under 35 USC 102(b) as being anticipated by Remelli et al. is hereby withdrawn. Applicants have included a proviso in the claims to overcome the rejection.

Rejection to claims under 35 USC 102(b) as being anticipated by Krause et al. is hereby withdrawn. Applicants have amended the claims to overcome the rejection.

Claims 1, 2, 5, 7-13, 15, 20-23, 25, 30, 32, and 33-37 remain rejected under 35 U.S.C 102(b) as being anticipated by Arcari et al. (DE 2700012). Applicants arguments have been fully considered but they are not persuasive. In the instant claims, X can be C(O), Y can be NH and Z can be alkyl. Therefore, the claims are still anticipated by the reference compound.

Claims 1, 2, 7-14, 18, 20-23, and 33-37 remain rejected under 35 U.S.C 102(b) as being anticipated by Hauck et al. Applicants arguments have been fully considered but they are not persuasive. A can be an alkylene group while X and Y can be a bond. The claims are still anticipated by the reference compound.

Claims 1, 2, 7-14, 18, 20-23, and 33-37 remain rejected under 35 U.S.C 102(b) as being anticipated by Yutilov et al. Applicants arguments have been fully considered but they are not persuasive. A can be an alkylene group while X and Y can be a bond. The claims are still anticipated by the reference compound.

Rejections to claims under 35 USC 102(b) as being anticipated by Scarponi et al, Stocker et al, Klutchko et al. are hereby withdrawn. Applicants have included a proviso in the claims to overcome the rejection.

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Claims 1-3, 5-13, 20-23, and 33-37 remain rejected under 35 U.S.C. 102(b) as being anticipated by Vincent et al. Applicants have not addressed the rejection.

Rejection to claims under 35 USC 102(b) as being anticipated by Clarke et al. is hereby withdrawn. Applicants' arguments have been found persuasive.

Rejections to claims under 35 USC 102(b) as being anticipated by Enari et al, Suzuki et al, Thorwart et al. are hereby withdrawn. Applicants have included a proviso in the claims to overcome the rejection.

Rejection to claims under 35 USC 102(b) as being anticipated by Casella et al. is hereby withdrawn. Applicants have amended the claims to overcome the rejection.

Claim Rejections - 35 USC § 103

The rejection to claims under 35 U.S.C 103(a) as being unpatentable over Arcari et al. (DE 2700012) is maintained for the same reason given in the above 102 rejection.

Claims 1-3, 5-15, 20-23, and 33-37 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Scarponi et al. (GB 2158440). Applicants' arguments have been fully considered but they are not persuasive. Although applicants have included an proviso to overcome the 102 rejection of the same reference, the proviso does not exclude all the possible compounds that can be made following the generic teachings in the reference. For example, R1 and R2 of the reference compounds can be a benzyl group which is not covered by the proviso. Thus, one of ordinary skill in the art would have been motivated to select the claimed compounds

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from the genus in the reference since such compounds would have been suggested by the reference as a whole. It has been held that a prior art disclosed genus of useful compounds is sufficient to render prima facie obvious a species falling within a genus.

Rejection to claims under 35 USC 102(a) as being unpatentable over Honma et al. is hereby withdrawn. Applicants have included a proviso in the claims to overcome the rejection.

Claims 1-3, 5-15, 20-23, 29-37 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Kureha et al. (EP 0589665).. Applicants' arguments have been fully considered but they are not persuasive. Although applicants have included an proviso to overcome the 102 rejection of the same reference, the proviso does not exclude all the possible compounds that can be made following the generic teachings in the reference. For example, R1 of the reference may not only be hydrogen. Thus, one of ordinary skill in the art would have been motivated to select the claimed compounds from the genus in the reference since such compounds would have been suggested by the reference as a whole. It has been held that a prior art disclosed genus of useful compounds is sufficient to render prima facie obvious a species falling within a genus.

Conclusion

1. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication should be directed to Examiner Hong Liu whose telephone number is (703) 306-5814. The examiner can normally be reached on Monday through Friday from 8:30 AM to 6:00 PM. If attempts to reach the examiner by the phone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached at (703) 308-4716. The fax phone number for this group is (703) 308-4734 for "unofficial" purposes and the actual number for **official** business is (703) 308-4556. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose number is (703) 308-1235.

hl
January 5, 2002


Mukund Shah
Supervisory Patent Examiner
Art Unit 1624